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| EXAMINER | |
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| CARTER, KENDRA D | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/626,069 | CAWTHON, GARRET D. | |
| | Examiner | Art Unit | |
| | KENDRA D. CARTER | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *39-53,57,60,74-76 and 87-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-53,57,60,74-76 and 87-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of May 12, 2008 made to the office action filed February 8, 2008. Claims 39-53,57,60,74-76 and 87-94 are pending.

The Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 39, 49, 57, 74, 76 and 88 as being unpatentable over Heilig were found persuasive, and thus withdrawn. Particularly, that the breathability of the Heilig composition is achieved through a physical interaction between the aerosol propellant and the polyethylene filament. Therefore, all further 35 U.S.C. 103(a) rejections are also withdrawn.

Due to the Applicant's arguments being persuasive the new 35 USC 112, first paragraph, and 103(a) rejections are made below. Therefore, since these are new rejections, a new Non-Final Office Action is made below and Applicant's arguments are not addressed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solid particulate material selected from the group zinc oxide, talc, calamine or kaolin, does not reasonably provide enablement for all solid particulate material. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of treating diaper rash comprising a composition including a fluid base material and a solid particulate material. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art;

(6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 39 is drawn to "a method for treating diaper rash ….wherein the composition includes: (1) a fluid base material comprising a member selected from the group consisting of mineral oil, silicone oil, an organic solvent, plant-based oil, water and mixtures thereof, and (2) a solid particulate material."

(2) The breadth of the claims:

Claim 39 embraces treating diaper rash with any solid particulate material. This The specification does not enable the treatment of diaper rash with any solid particulate material.

(3) The state of the prior art:

The state of the art regarding treating diaper rash with any solid particulate material is very low or do not exist.

(4) The predictability or unpredictability of the art:

The predictability treating diaper rash with any solid particulate material is relatively low. Therefore, to one skilled in the art, treating diaper rash with any solid particulate material is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high. Melloh et al. (US 4,307,089) teaches that the solid particulate, sodium pyrithione irritates skin in 40 and 48% solutions (see column 1, line 44-48). Thus, all solid particulates are not useful to treat diaper rash because they can irritate the skin.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the treatment of diaper rash with any solid particulate material is completely lacking. The specification teaches that the composition comprises at least about 1% solid particulate material, in which zinc oxide is preferred (see page 14, second paragraph). Zinc oxide can be substituted or combined with other solids such as talc, calamine or kaolin (see page 17, lines 3-5). The specification as filed does not speak on or show any working examples any studies performed that demonstrate that any solid particulate material can treat diaper rash. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on treating diaper rash with any solid particulate material. As discussed above the specification fails to provide any support for treating diaper rash with any solid particulate material. Applicant fails to provide any information sufficient to

practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for treating diaper rash with a solid particulate material selected from the group zinc oxide, talc, calamine or kaolin, but not for any solid particulate material.

## *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**(1) Claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), and in further view of Heilig (US 3,079,299).**

Paul et al. teaches an absorbent article for absorbing body fluids and exudates, such as disposable diapers and adult incontinence garments (see column 1, lines 19-23), which includes a lotion formulation or treatment composition which provides a skin health benefit, and/or have a reduced viability of microorganisms (i.e. diaper rash treatment system; see column 2, lines 56-58). In general, when wetness increases, the treatment composition will transfer from the topsheet to the skin to form a protective barrier (i.e. leaving the composition on the skin treatment area to form a coating; see column 24, lines 14-16) The lotion formulation includes an emollient, a wax, optionally a viscosity enhancer, and other ingredients (see column 13, lines 57-59 and 64). The emollients act as lubricants to reduce the abrasiveness of the topsheet to the skin and, upon transfer to the skin, help to maintain the soft, smooth and pliable appearance of the skin (see column 13, lines 66, 67 to column 14, lines 1 and 2). Suitable emollients include vegetable based oils, mineral oils, natural or synthetic oils, silicone oils, lanolin and lanolin derivatives, kaolin and kaolin derivatives and the like and mixture thereof (se column 14, lines 3-5; address claims 39, 44, 48, 49, 57). The wax in the lotion formulations primarily functions as an immobilizing agent for the emollient and any active ingredient. In addition to immobilizing the emollient and reducing it's tendency to migrate, the wax in the lotion formulation provides a tackiness, which improves the transfer to the skin of the wearer. The presence of the wax also modifies the mode of transfer in that the lotion tends to fracture or flake off instead of actually rubbing off onto the skin of the wearer which can lead to improved transfer to the skin. The wax may further function as an emollient, occlusive agent, moisturizer, barrier enhancer and

combinations thereof (see column 14, lines 31-43). Suitable waxes include beeswax, C30 alkyl dimethicone, jojoba oil, microcrystalline wax, paraffin and mixtures thereof (see column 14, lines 44, 47, 49, 52-54, and 59; addresses claims 45, 46, 52, 53 and 57). A viscosity enhancer increases the viscosity to help stabilize the formulation on the bodyfacing surface on the topsheet and reduce migration and improve transfer to the skin (i.e. a fluid composition having a viscosity sufficiently high that the coating does not run off of the skin treatment area; see column 15, lines 6-9). A suitable viscosity enhancer is polyethylene, talc or mixtures thereof (see column 15, lines 18 and 20; addresses claim 48). Active ingredients such as diaper rash skin protectants, which protect the injured or exposed skin or mucous membrane surface from harmful or annoying stimuli are included (see column 15, lines 31-36). Suitable active ingredients include calamine, dimethicone, cod liver oil, kaolin and its derivatives, lanolin and its derivatives, mineral oil, talc, zinc oxide and mixture thereof from about 0.10 to about 95 weight percent (see column 15, lines 40-44; addresses claims 39, 40, 47-50, 53 and 57). To further enhance the benefit to the wearer, antimicrobial, antifungal, antiseptic, colarants, and fragrances can be added (see column 15, lines 54, 55, 61, 62, and column 16 lines 6 and 7; addresses claim 57). The treatment composition is added to the topsheet by spraying (see column 23, lines 59 and 60).

Paul et al. does not teach that the composition is sprayed on the skin treatment area to provide a moisture barrier over the skin from an atomizing spray dispenser (claim 39), particularly a pump spray (claims 74, 75 and 87). Paul et al. also does not

specifically teach wherein the fluid composition has a viscosity sufficiently low to allow the composition to be atomized upon passage through the atomizing spray dispenser (claim 39). Paul et al. also does not teach wherein the fluid base material comprises a volatile compound that evaporates after passage through the atomizing spray dispenser (claim 76).

Goldberg et al. teaches an antiperspirant/deodorant composition which may be in the form of a pump pray, cream or lotion (see column 2, lines 1-6). The lotions are liquid based with suitable liquids such as silicones, glycols and emollients (see column 2, lines 15-17). Silicones include dimethicone and cyclomethicone, which provides a pleasant layer on the skin which enhances feel (see column 4, lines 42-49). The composition also comprises absorbants such as talc, starch and zinc oxide (see column 5, lines 25-31). The composition can also comprise a drying enhancer that enables the composition to dry more quickly such as isopropyl alcohol or ethanol (see column 6, lines 4-7).

Heilig teaches a self-propelling medicinal ointment composition and method of application to treat diaper rash, by rapidly releasing the medicament in the form of a spray or mist to the part of the body to be treated (see title and column 1, lines 11-16, 30-36 and see column 5, lines 42-45).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al. and wherein the composition is sprayed on the skin treatment area to provide a moisture barrier over the skin from an atomizing spray dispenser (claim 39), particularly a pump spray (claims 74, 75 and 87) because of the following teachings: 1) Paul et al. teaches the Applicant's diaper rash composition that is sprayed on the diaper and then transferred to the treated area to provide a barrier over the skin (see column 2, lines 56-58; see column 23, lines 59 and 60; and column 24, lines 14-16); 2) Heilig et al. teaches that by spraying the composition directly on the treated area, the diaper rash treatment is released rapidly (see title and column 1, lines 11-16, 30-36 and see column 5, lines 42-45); and 3) Goldberg et al. teaches a composition comprising similar components as the Applicant, such as a silicone oil and a solid particulate material, can be formulated into a pump spray (see column 2, lines 1-6; see column 4, lines 42-49; and see column 5, lines 25-31). Thus, the composition of Paul et al. would provide a protective barrier on the skin faster if applied by a spray directly to the effected area then by transfer from the diaper. In regards to the pump spray, Paul et al. and Goldberg et al. has demonstrated that the Applicant's composition can be sprayed, in which Goldberg et al. teaches the pump spray. In regards to the moisture barrier obtained over the skin, Paul et al. teaches that the composition provides a protective barrier over the skin, as well as it is known in the art that it is desirable to prevent the urine (i.e. moisture) from the touching the skin on the effected area to enhance healing or/and to prevent the formation of bacteria that causes the rash. Additionally, Paul et al. teaches the Applicant's composition.

"Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al. and wherein the composition comprises a volatile compound that evaporates after passage through the atomizing spray dispenser (claim 76) because of the following teaching: 1) Goldberg et al. teaches that a drying enhancer such as ethanol (i.e. a volatile compound) enables the composition to dry more quickly (see column 6, lines 4-7); and 2) Heilig et al. teaches that by spraying the composition directly on the treated area, the diaper rash treatment is released rapidly (see title and column 1, lines 11-16, 30-36 and see column 5, lines 42-45). Thus, in order to apply the treatment more rapidly, one skilled in the art would further apply a drying enhancing agent such that the composition would be immediately effective upon leaving the pump spray.

In regards to wherein the fluid composition has a viscosity sufficiently low to allow the composition to be atomized upon passage through the atomizing spray dispenser

(claim 39), Paul et al. and Goldberg et al. has demonstrated that the Applicant's composition can be sprayed, thus the limitation is obviously met.

**(2) Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), and in further view of Heilig (US 3,079,299) as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above, in further view of Clark et al. (US 6,103,245).**

The teachings of Paul et al., Goldberg et al., and Heilig are as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above.

Paul et al., Goldberg et al., and Heilig does not teach zinc oxide as the particulate or its average particle size (claims 40-43 and 60).

Clark et al. teaches a composition for superior, longer-lasting barrier formulation as a protective barrier for incontinent patients along with managing diaper rash in humans (see column 4, lines 55-59). The inorganic barrier component zinc oxide is used and should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). Zinc oxide has a mild astringent, protective and antiseptic action. Thus it is often used in the treatment of skin disorders and a number of epidermal infections (see column 7, lines 11-14).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al., Goldberg et al., and Heilig and the average particle size of zinc oxide as disclosed in claims 40-43 and 60 because Clark et al. teaches that zinc oxide should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). One skilled in the art would be able to determine the optimal particle size of zinc oxide by routine experimentation.

**(3) Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), and in further view of Heilig (US 3,079,299) as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above, in further view of Steuart et al. (US 5,330,756).**

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

The teachings of Paul et al., Goldberg et al., and Heilig are as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above.

Paul et al., Goldberg et al., and Heilig does not teach calendula extract, chamomile extract, comfrey extract, or a plant based oil.

Steuart et al. teaches a method of treating a variety of skin conditions, such as diaper rash (see column 6, lines 19 and 20) with a therapeutic formulation comprising concentrated fluid plant extracts such as *S. officinale* (see abstract, lines 4, 5, and 11-14; column 4, line 45; and column 5, lines 29-32), and olive oil, castor oil, and jojoba oil (i.e. plant based oils; see column 10, example B2 and B3). Alcohol or glycol extract solutions of *S. officinale*, which is called "comfrey" has been recognized for decades for its healing properties, particularly for its ability to stimulate epithelial development externally in the case of skin damage (see column 1, lines 21, 21, and 61-64). The formulations are formulated into a spray (see column 5, lines 50-53). In oil and water emulsion formulations, the oil is the dispersed phase for the purpose of protecting, moisturizing, and stimulating the healing processes of skin or mucous membrane (see column 5, lines 40-44).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al., Goldberg et al., and Heilig and comfrey extract and a plant based oil because Steuart et al. teaches a method of treating diaper rash with and comfrey extract in a variety of plant based oils. The benefit of using comfrey extra in an oil is because of the following teachings by Steuart et al.: (1) comfrey extracts have been recognized for decades for its healing properties,

particularly for its ability to stimulate epithelial development externally in the case of skin damage (see column 1, lines 21, 21, and 61-64); and (2) the oil is the dispersed phase for the purpose of protecting, moisturizing, and stimulating the healing processes of skin or mucous membrane (see column 5, lines 40-44). Additionally, since the composition can be formulated into a spray, the above ingredients can be used in the method of Paul et al., Goldberg et al., and Heilig.

**(4) Claims 74, 75, 87, 89, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), and in further view of Heilig (US 3,079,299) as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above, in further view of Ando (US 5,881,925).**

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

The teachings of Paul et al., Goldberg et al., and Heilig are as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above.

Paul et al., Goldberg et al., and Heilig does not teach a pump spray dispenser and a pressure release device (claims 74, 75 and 87). A piston-style dispenser, wherein pressure is maintained on the composition by pressure of the piston is also not taught (claim 89). Lastly, a manually actuated or reciprocating actuator spray delivery mechanism is not taught (claims 93 and 94).

Ando teaches a atomizer of the reciprocating pump type with a push button that is capable of being pressed with a finger, a piston which is pushed down by pressing the push button, a pressure chamber formed with the cylinder and the piston that has an inlet leading to the inside of the container and an outlet leading to the internal passage in the push button, the outlet of the pressure chamber moves against the force increased when the piston is pressed by the push button to open the above outlet (see column 1, lines 46 and 52-64; addresses claims 74, 75, 87, 89 and 94). Conventionally, atomizers that spray a mixture of liquid and powder are available such that the user shakes the mixture well in the container and then the push button is pressed. The atomizing tube is pushed in and opens the valve and the mixture is atomized through the nozzle (see column 1, lines 13, 14, and 18-23; addresses claim 93). The reciprocating pump type device provides an atomizer that is capable of stirring a mixture sufficiently and atomizing both powder and a liquid when used (see column 1, lines 24-32).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and a reciprocating pump type device with a piston-style dispenser, wherein pressure is maintained on the composition by pressure of the piston because Ando teaches the following: (1) reciprocating pump type with a push button that is capable of being pressed with a finger, a piston which is pushed down by pressing the push button, a pressure chamber formed with the cylinder

and the piston that has an inlet leading to the inside of the container and an outlet leading to the internal passage in the push button, the outlet of the pressure chamber moves against the force increased when the piston is pressed by the push button to open the above outlet (see column 1, lines 46 and 52-64); and (2) the reciprocating pump type device provides an atomizer that is capable of stirring a mixture sufficiently and atomizing both powder and a liquid when used (see column 1, lines 24-32). Being that the applicant's method comprises a liquid and solid, this device would be suitable to deliver the diaper rash composition.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al., Goldberg et al., and Heilig and a spray delivery comprising a manually actuated spray delivery mechanism is because as taught by Ando, it is the conventional way to atomize liquid and solid compositions (see column 1, lines 13, 14, and 18-23). Being that Paul et al., Goldberg et al., Heilig and Applicant's method comprises a liquid and solid, this device would be suitable to deliver the diaper rash composition.

**(5) Claims 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), and in further view of Heilig (US 3,079,299) as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above, in further view of Davies et al. (US 5,169,037).**

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

The teachings of Paul et al., Goldberg et al., and Heilig are as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above.

Paul et al., Goldberg et al., and Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag (claims 90 and 91).

Davies et al. teaches a product dispenser with a product bag. Pressure in the container surrounding the bag determines the dispensing pressure (see abstract, lines 1-4; addresses claims 90 and 91). The product bag is constructed of a suitable barrier material, which may take the form of a gas impervious material (see column 2, lines 6-8 and 31-33) and the height should be approximately equal to the different between the in inside can height (see column 7, line 51 and 52). The pressure regulating system is configured so as to permit product dispensing with an unrestricted orientation of the product dispenser while avoiding loss in product dispensing pressure or interruption of product dispensing (see column 2, lines 59-64). Additionally, the product has the following advantages: (1) the capability of choosing a starting pressure depending upon the amount of product fill in the product bag together with a given can size and product

bag size; and (2) off the shelf actuators which are cheaper and less prone to clogging than special units designed for wide range of pressure in the dispensing of the product can be used (see column 14, lines 36-45).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al., Goldberg et al., and Heilig and a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag because Davies et al. teaches the above bag-in-can style dispenser, which permits product dispensing with an unrestricted orientation of the product dispenser while avoiding loss in product dispensing pressure or interruption of product dispensing (see column 2, lines 59-64). Additionally, the product has the following advantages: (1) the capability of choosing a starting pressure depending upon the amount of product fill in the product bag together with a given can size and product bag size; and (2) off the shelf actuators which are cheaper and less prone to clogging than special units designed for wide range of pressure in the dispensing of the product can be used (see column 14, lines 36-45).

**(6) Claims 90 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), and in**

**further view of Heilig (US 3,079,299) as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above, in further view of Hanson et al. (US 5,249,747).**

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

The teachings of Paul et al., Goldberg et al., and Heilig are as applied to claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 above.

Paul et al., Goldberg et al., and Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can. Also, an elastic shape-memory bag wherein the pressure is maintained upon the composition by maintaining the bag in an expanded state is not taught.

Hanson et al. teaches a dispensing system for viscous fluids having a viscosity of greater than 60 cps (see column 3, lines 44-48), particularly vegetable oil containing compositions in closed pressurized containers such as bladder packs (see column 2, lines 8-13).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al., Goldberg et al., and Heilig and the specific bag-in-can-style dispenser, bladder pack container (Applicant refers to an elastic shape-memory bag wherein the pressure is maintained upon the composition

by maintaining the bag in an expanded state as a bladder pack container on page 25, paragraph 1, lines 6-8) because Hanson et al. teaches a dispensing system for viscous vegetable oil containing compositions in closed pressurized containers such as bladder packs (see column 2, lines 8-13). Being that Paul et al. teaches a composition comprising a viscosity enhancer, which helps stabilize the formulation on the surface (see column 15, lines 6-9), this device would be suitable to deliver the diaper rash composition.

## ***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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